GRONEK & ARMSTRONG

ATTORNEYS AT LAW

98TH FLOOR - SEARS TOWER 233 SOUTH WACKER DRIVE CHICAGO, ILLINOIS 60606

DENNIS M. GRONEK ROBERT E. ARMSTRONG PAUL J. WISNIEWSKI DEBORAH L. RUSS JACQUELINE P. KULER TEL: (312) 655-1800 FAX: (312) 655-1808

1500 2 4 2000 1 18370 - 1

September 15, 2003

Office of Nutritional Products Labeling and Dietary Supplements (HFS-810) Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Pkwy College Park, MD 20740

Re: Notification for Statements on Dietary Supplement Labels

Dear Sir/Madam:

This firm represents Synergy Worldwide, Orem, Utah, a distributor of dietary supplement products (hereafter "Synergy"). Synergy has requested that we notify your Agency on its behalf of the inclusion of statements of nutritional support on a dietary supplement product label.

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. §343(r)(6), and in accordance with the authorized provisions of 21 CFR §101.93(a), your Agency is hereby notified that Synergy has made statements of "nutritional support", as described in 21 U.S.C. §343(r)(6)(A), for a dietary supplement as follows:

Product Name

Label Statement(s)

Body Guard - 120 capsules

Immune support; Body Guard is formulated from the finest deep-sea shark liver oil to provide maximum protection against oxidative stress, boost the immune system, and promote cardiovascular health.

Two copies of this notification are enclosed with this original document.

978 0162 LET 129412

The undersigned hereby certifies on behalf of Synergy that the information contained in this correspondence is complete and accurate.

Sincerely yours,

GRONEK & ARMSTRONG

Robert E. Armstrong

REA:

pr

Enclosures

CC: Synergy Worldwide